

### **Remarks**

Applicants note that Claims 17-23 have been withdrawn from further consideration. Claims 17-23 have been cancelled. Applicants, however, reserve the right to file one or more divisional applications directed to Claims 17-23.

Applicants have amended Claims 9 and 11 to further clarify the recitation to “potassium permeable channel,” so that all antecedent basin problems have been resolved.

### **Response to 35 USC § 112, 1<sup>st</sup> Paragraph Rejections**

Claims 9-16 have been rejected under 35 U.S.C. 112, first paragraph. Applicants respectfully submit that as a result of the amendment to claim 9 the rejection under 35 U.S.C. §112, first paragraph is now obviated. Specifically, the Applicants have identified that the isolated and purified protein is of SEQ ID No: 4, or a functionally equivalent derivative having at least 85% identity to SEQ ID No: 4. Support for this amendment can be found on page 26, lines 22-24, and page 17, lines 18-21. Claim 16 has been cancelled as being redundant.

Applicants respectfully submit that the Specification clearly demonstrates both mouse and human TASK proteins, which share high overall sequence conservation of 85%. Applicants submit that one skilled in the art would readily recognize a functionally equivalent derivative of the TASK channel protein, which is 85% homologous to SEQ ID No: 4.

It is respectfully submitted that as a result of this amendment, the Applicants have directed Claim 9 to include those proteins, which share 85% sequence identity to SEQ ID No: 4, wherein these will further contain a defined set of P domains and transmembrane segments. In view of this claim amendment, and in further view of the specific guidance and working

examples provided in the Specification, one skilled in the art would be able to practice the invention.

The Applicants submit that one skilled in the art readily understands that conservative substitutions may be made to a sequence without changing either structural or functional aspects of the polypeptide. Such a conservative substitution generally results when one amino acid of like hydrophobicity, charge, and orientation is substituted with another amino acid having the same properties. Clearly, one skilled in the art, after studying the Applicants' Specification, including Figure 8, would readily recognize the proper conditions to perform a conservative substitution so that a functionally equivalent derivative having 85% homology to SEQ ID No: 4 could be isolated and identified.

In view of the foregoing, Applicants respectfully submit that amended Claim 9 does not require undue experimentation.

#### **Claim Rejections Under 35 U.S.C. §102**

Claim 9 has been rejected under 35 U.S.C. 102(b) as being anticipated by Ketchum et al. (Nature 1995 Aug; 376(6543): 690-695). Applicants respectfully submit that as a result of the amendment to Claim 9, the rejection under Ketchum et al. is now obviated. Specifically, the Applicants have incorporated SEQ ID No: 4, and/or functionally equivalent derivatives thereof having 85% identity to SEQ ID No: 4, into claim 9. As a result, Ketchum et al. fails to teach a TASK potassium channel having the Applicants' sequence. Withdrawal of the rejection is respectfully requested.

Claims 9-14 have been rejected under 35 U.S.C. 102(e) as being anticipated by Price et al. (U.S. Patent No. 5,559,026). Applicants respectfully submit that as a result of the amendment to Claim 9, the rejection of Claims 9-14 is now obviated. Applicants respectfully

submit that the sequence described in Price et al. is structurally dissimilar from the Applicants TASK channel protein. Namely, Price et al. has identified a 618 amino acid polypeptide and a 336 amino acid polypeptide, which share no significant homology with the Applicants' SEQ ID No: 4. In view of these significant differences, Applicants respectfully submit that the protein described in Price et al., inherently fails to show a protein that “ lacks outward rectifying capacity at 98mM, lacks intrinsic voltage and lacks voltage and time sensitivities.”

Nowhere in Price et al., and the protein described therein, is there an indication that the “Price protein” is regulated by extracellular pH. In sharp contrast, the Applicants have demonstrated that TASK is regulated by extracellular pH. As a result, the Applicants respectfully submit that the sequence described in the Applicants' amended Claim 9 is not inherent in light of the teachings described in Price et al.

The Applicants invite the examiner's attention to the case of In re Deule, 34 USPQ2d 1210 (Fed. Cir. 1995), where the court held that the rejection of claims drawn to a particular DNA sequence was improper when the reference used in the prior rejection failed to teach the DNA molecules.

Applicants respectfully submit that the facts of In re Deule are analogous to the facts of this case. The court In re Deule noted that:

“While the general idea of the claimed molecules, their function, and their general chemical nature may have been obvious under Bohlen's teachings, and the knowledge that some genes existed may have been clear, the precise cDNA molecules of Claims 5 and 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules. The redundancy of the genetic code precluded contemplation of or focus on the specific cDNA molecules of Claims 5 and 7... Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it. Thus, a *fortiori*, Bohlen's disclosure of the N-terminal portion of a protein, which the PTO urges is the same as HBGF, would not

have suggested the particular cDNA molecules defined by Claims 5 and 7. This is so even though one skilled in the art knew that some DNA, albeit not in purified and isolated form, did exist. The compounds of Claims 5 and 7 are specific compounds not suggested by the prior art.”

Similar to the case of In re Deule, , the current application describes a completely different sequence than that disclosed in Price et al. Specifically, Price et al teach a 618 and 336 amino acid, while Applicants’ SEQ ID No: 4 is 394 amino acids.

As an example of the vastly different structural, and hence functional, properties of the Applicants’ SEQ ID No: 4, as compared to the amino acids of Price et al., the Examiner is asked to compare the terminal residues of the amino acids. As an example, the Applicants’ 5 terminal residues in both SEQ ID No: 4 and 5 are comprised of Arg, Arg, Ser, Ser, and Val, while the terminal residues of the two polypeptide of Price et al. are Ala, Ala Aa, Ala, and Gly; and Asn, Arg, Ala, Phe and Lys. One skilled in the art would readily recognize that the Applicants’ 5 terminal residues have 2 positively charged R groups, followed by 2 polar uncharged groups, and finished with a nonpolar aliphatec group. In contrast, Price et al.’s terminal residues are 5 non-polar aliphatil groups in the first protein; and a polar uncharged, a positively charged R, a non-polar aliphatil, an aromatil, and a positive R group on the second protein of Price et al.

With this background, it is respectfully submitted that, “in relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to support the determination that the alleged inherent characteristic necessarily flows from the teaching of the applied prior art.” Ex parte Levy 17 USPQ 2d 1461, 1464 (Ed. Pat. App. 1990). The mere fact that a certain thing may result from a set of circumstances is not enough to establish inherency. In re Oelrich, 212 USPQ 323, 326 (CCPA 1981).

In view of these holdings, and in further view of the vast structural differences between the Applicants' TASK channel protein and the proteins of Price et al., the Applicants submit that the rejection is now obviated. Withdrawal of the rejection is respectfully requested.

Claim 9 has been rejected under 35 U.S.C. 102(a) as being anticipated by Reid JD et al. Applicants respectfully submit that as a result of the amendment to claim 9, to incorporate SEQ ID No. 4, the rejection is now obviated. Namely, nowhere in Reid et al. is there a teaching or discussion of the Applicants' SEQ ID No. 4 or a functionally equivalent sequencing having 85% conserved identity to that of SEQ ID No. 4. Withdrawal of the rejection is respectfully requested.

Claims 9, 10 and 12 have been rejected under 35 U.S.C. 102(a) as being anticipated by Lesage et al. Applicants respectfully submit that Lesage et al. fails to teach the protein comprised of SEQ ID No. 4 and as a result fails to anticipate amended claim 9. Applicants further note that the inventors identified in the pending application are the authors of Lesage et al. Consequently, it is respectfully submitted that the inventors clearly invented the relevant subject matter of the pending application prior to the authorship of Lesage et al. Withdrawal of the rejection is respectfully requested.

In view of the foregoing, Applicants respectfully submit that the application is now in condition for allowance which action is respectfully requested.

Respectfully submitted,



T. Daniel Christenbury  
Reg. No. 31,750  
Attorney for Applicants

TDC/ks  
(215)656-3381